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EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,135	HIRABAYASHI ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Claims 4-11 are pending.

Applicant's traversal and the amendment to claims 4 and 5 in paper filed on 12/27/04 is acknowledged and considered.

Claim Objections

Claim 4 is objected to because of the following informalities: several periods in the claim. Suggest replacing the period after "1" on line 3 and "2" on line 8 with --) --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'inducing interferon chiefly in the liver comprising intravenously, transmucosally, or hepatic intra-arterially administering to a human a complex of cationic

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liposome with 1 µg to 50 mg of Poly I:C which has a mean length within the range of 100 to 500 bp once through three times a day, every day, every other day, or on a weekly or fortnightly basis' in amended claim 5 and claims dependent therefrom (claims 10 and 11) is not supported by the as-filed specification. Claim 9 (which is dependent from claim 5) is not included in the rejection because the specification provides support for using the method in claim 9 for treating hepatitis. Applicants do not cite where the limitation in the amended claim is supported in the specification and there appears to be no written description of this limitation in the application as filed. See MPEP § 2163.06. Claim 5 was directed to inducing interferon specifically in the liver of a human for treating hepatitis, however, the amended claim is now broader than treating hepatitis in a human by inducing interferon chiefly in the liver.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the hepatitis is hepatitis C" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Desmyter et al. (Texas Reports on Biology and Medicine 35:516-522, 1977) taken with Yano et al., (YANO 1) (US Patent No. 5,298,614, cited on a prior PTO-892).

Desmyter teaches that interferon and interferon inducers (e.g., Poly IC) have been studied for treating hepatitis in a patient and chimpanzees (page 516). Desmyter teaches that Poly IC complexes with poly-L-lysine and carboxymethylcellulose were administered to chimpanzees

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that have a chronic hepatitis B infection (page 518). Two courses with the complexes were given to the chimps: 3mg/kg daily for one week and every other day for another week and, six month later, 3 mg/kg daily for 2 weeks and every other day for a total of 7 weeks (page 518). Both courses resulted in treatment of the hepatitis B infection (pages 518-519). Desmyter teaches that the administration of Poly IC to the mammals results in direct action of interferon in the liver (page 519).

However, Desmyter does not specifically teach intravenously, hepatic intra-arterially, or transmucosally administering a complex comprising administering a cationic liposome with 1 μ g to 50 mg of poly IC, which has a mean length within the range of 100 to 500bp.

However, at the time the invention was made, YANO 1 teaches that poly I: poly C is a substance having interferon induction action and can be used for treating viral infections (abstract and column 3, lines 32-40). YANO 1 further teaches that the substance can be used as a pharmaceutical substance in humans (column 16). YANO 1 further teaches that when the chain length is limited to certain ranges, the resulting substance exhibit desired physiological activity with markedly less toxicity (column 4, lines 31-39). YANO 1 teaches that the fact that the control of molecular size of nucleic acid polymer within a specified range is the primarily important factor for remarkable reduction of toxicity of poly I: poly C and the preferred molecular size for using poly I: poly C is from 100 to 600 base numbers (column 11, lines 13-34). YANO 1 further teaches that the dsRNA can be delivered to an individual using different routes of delivery, including subcutaneous, intramuscular, or intravenous (column 18, line 32-46).

Therefore, at the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter and YANO1 to use the complex comprising a cationic liposome with 1 μ g to 50 mg of poly IC which has a mean length within the range of 100 to 500 bp; once, every day, every other day, weekly, or bi-weekly to induce interferon chiefly in the liver in a human by transmucosally or intravenously administering the complex to the human. One of ordinary skill in the art would have been motivated to combine the teachings and use the complex to induce an interferon response in a human because the prior art (e.g., YANO 1 and Desmyter) teaches that the complex can be used to induce an interferon response in a human resulting in an anti-viral or an anti-tumor activity in the human. In addition, in view of using the method taught by Desmyter and the routes taught by YANO 1, one of ordinary skill in the art would have expected that by intravenously or transmucosally administering Poly IC to a human would induce interferon chiefly in the liver of a human with a reasonable expectation of success. One of ordinary skill in the art would have been motivated, as a matter of designer choice, to use 3mg of Poly IC to induce interferon chiefly in a human because the prior art (e.g., Desmyter) teaches one of ordinary skill in the art that delivering 3mg of Poly IC to a mammal was a well known concentration for delivering Poly IC to a mammal and the specification does not teach any unexpected result using 3 mg of Poly IC, which falls within the range of 1 μ g to 50 mg of Poly IC in the method. One of ordinary skill in the art would have been motivated to use Poly IC which has a mean length within the range of 100 to 500bp as taught by Yano 1 for inducing interferon chiefly in the liver of a human because this range displays reduce toxicity of the double stranded RNA in vivo. One of ordinary skill in the art would have been motivated, as a matter of designer choice, to deliver the complex once, every

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day, every other day, weekly, or bi-weekly because the prior art (Desmyter) teaches one of ordinary skill in the art that these routines are common routines for delivering Poly IC to a mammal and the specification does not teach any unexpected result by delivering the complex once, every day, every other day, weekly, or bi-weekly.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Desmyter et al. (Texas Reports on Biology and Medicine 35:516-522, 1977) taken with Yano et al., (YANO 1) (US Patent No. 5,298,614, cited on a prior PTO-892) as applied to claim 5 above, and further in view of Bever et al. (Journal of Interferon Research, 5: 423-428, 1985).

However, Desmyter and YANO 1 do not specifically teach treating a human using the complex.

However, at the time invention was made, Bever teaches i.v. administration of 100 µg/kg Poly IC in humans, wherein the administration of Poly IC produced substantial levels of IFN (pages 86-89). Bever teaches that substantial levels of IFN were produced when Poly IC was administered weekly, biweekly and monthly (page 86). In addition, in view of the levels of IFN produced by administering Poly IC to a human taught by the prior art (e.g., Desmyter and Bever), one of ordinary skill in the art would have reasonably expected that Poly IC could be used to treat hepatitis in a human with a reasonable expectation of success.

At the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter, YANO 1 and Bever to treat hepatitis in a

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human using intravenous or transmucosal administration of a complex comprising a cationic liposome with 1 µg to 50 mg of poly IC which has a mean length within the range of 100 to 500 bp; once, every day, every other day, weekly, or bi-weekly and inducing interferon chiefly in the liver in a human. One of ordinary skill in the art would have been motivated to use the complex for treating hepatitis in a human because Poly IC was well known to one of ordinary skill in the art for inducing interferon in a patient for treating hepatitis. In addition, in view of the prior art teaching the amount of interferon produced in a human using Poly IC (e.g., Bever and Desmyter), one of ordinary skill in the art would have reasonably expected that Poly IC could be used to treat hepatitis in a human with a reasonable expectation of success. In addition, one of ordinary skill in the art would have been motivated to use poly I:C at either 3mg or 100 µg of Poly IC for treating hepatitis in a human because the prior art teaches one of ordinary skill in the art that these concentrations of Poly IC would produce a sufficient amount of interferon *in vivo* to treat hepatitis in a human. One of ordinary skill in the art would have been motivated to use intravenous or transmucosal administration to deliver the complex to treat hepatitis in a human because the prior art teaches one of ordinary skill in the art that both routes of administration produce enough IFN to treat hepatitis in a human. One of ordinary skill in the art would have been motivated, as a matter of designer choice, to deliver the complex once, every day, every other day, weekly, bi-weekly to treat hepatitis in a human because the prior art teaches one of ordinary skill in the art that these regimens would produce enough IFN to treat hepatitis in a human. One of ordinary skill in the art would have been motivated to use Poly IC which has a mean length within the range of 100 to 500bp of Poly IC as taught by YANO 1 for treating

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hepatitis in a human because this range displays reduced toxicity of the double stranded RNA in vivo.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 5 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desmyter et al. (Texas Reports on Biology and Medicine 35:516-522, 1977) taken with Yano et al., (YANO 1) (US Patent No. 5,298,614, cited on prior 892) as applied to claim 5 above, and further in view of YANO 2 (EP 0685457A1, cited on an IDS).

However, Desmyter and YANO1 do not specifically teach using (2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid, e.g., lecithin in the method.

However, at the time the invention was made, YANO 2 teaches using the complex (2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid, e.g., lecithin) to administer double stranded RNA to an individual. In addition, YANO 2 teaches that using the complex reduces toxicity of the double stranded RNA in vivo and improves the uptake efficiency of the double stranded RNA into cells ('457, abstract and pages 2-11). YANO 2 teaches that the complex can be delivered intravenously, intrarterially, locally, and rectally (page 16).

Therefore, at the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter, YANO 1, and YANO 2 to use 2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid (e.g., lecithin) with poly I:C in the method. One of ordinary skill in the art would have been motivated to use 2-O-

(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid (e.g., lecithin) with poly I:C for inducing interferon chiefly in the liver of a human because the lipid reduces toxicity of the double stranded RNA in vivo and improves the uptake efficiency of the double stranded RNA (Poly IC) into cells of an individual.

In addition, at the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter, YANO 1 and YANO 2 to use i.v., intra-hepatic intra-arterial or transmucosal administration of the complex to induce interferon chiefly in the liver in a human. One of ordinary skill in the art would have been motivated to use the administration routes to deliver the complex to induce interferon chiefly in the liver in a human because the prior art teaches one of ordinary skill in the art that the routes of administration listed above are well known to one of ordinary skill in the art for delivering Poly IC to a human, which would result in inducing interferon chiefly in the liver as taught by Desmyter. In addition, one of ordinary skill in the art would have been motivated to use hepatic intra-arterial administration because hepatitis results in the inflammation of the liver and one of ordinary skill in the art would determine that the liver would be the target area for inducing interferon using Poly IC.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desmyter et al. (Texas Reports on Biology and Medicine 35:516-522, 1977) taken with Yano et al., (YANO 1) (US Patent No. 5,298,614, cited on prior 892) and Bever et al. (Journal of

Interferon Research, 5: 423-428, 1985) as applied to claim 4 above, and further in view of YANO 2 (EP 06854557A1, IDS).

However, Desmyter, YANO 1 and Bever do not specifically teach using the complex (2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid, e.g., lecithin) in the method.

At the time the invention was made, YANO 2 teaches using a complex (2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid, e.g., lecithin) to administer double stranded RNA to an individual and that using the lipid reduces toxicity of the double stranded RNA and improves the uptake efficiency of the double stranded RNA into cells ('457, abstract and pages 2-11). YANO 2 teaches that the complex can be delivered intravenously, intrarterially, locally, and rectally (page 16).

At the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter, YANO 1, and Bever in further view of YANO 2 to use 2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid (e.g., lecithin) with poly I:C in the method. One of ordinary skill in the art would have been motivated to use 2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid (e.g., lecithin) with poly I:C for treating hepatitis in a human because the lipid reduces toxicity of the double stranded RNA in vivo and improves the uptake efficiency of the double stranded RNA into cells of the individual.

In addition, at the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter, YANO 1 and Bever to use i.v., hepatic intra-arterial, or transmucosal administration of the complex to treat hepatitis in a

human. One of ordinary skill in the art would have been motivated to use the administration routes to deliver the complex to treat hepatitis in a human because the prior art teaches one of ordinary skill in the art that these routes of administration would produce enough IFN to treat hepatitis in a human and these administration routes were well known to one of ordinary skill in the art for delivering Poly IC to a mammal. In addition, one of ordinary skill in the art would have been motivated to use hepatic intra-arterial administration because hepatitis results in the inflammation of the liver and one of ordinary skill in the art would determine that the liver would be the target area for inducing interferon using Poly IC.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Desmyter et al. (Texas Reports on Biology and Medicine 35:516-522, 1977) taken with Yano et al., (YANO 1) (US Patent No. 5,298,614, cited on prior 892) in further view of Bever et al. (Journal of Interferon Research, 5: 423-428, 1985) as applied to claim 4 above, and further in view of Liaw (J. Gastroenterol. Hepatol. 1997, 12:S346-53).

However, Desmyter, YANO 1 and Bever do not specifically teach using the method to treat hepatitis C.

However, at the invention was made, Liaw teaches that interferon (IFN) is approved and widely used for treating HBV, HCV, and HDV (page S346).

At the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter, YANO 1 and Bever in further view of

Liaw to use Poly IC in a method for treating hepatitis C in a human. One of ordinary skill in the art would have been motivated to combine the teachings and use Poly IC in the method to treat hepatitis C in a human because Liaw teaches that IFN is approved for treating HBV and HCV and Poly IC is known to one of ordinary skill in the art for producing an effective amount of IFN in vivo for treating hepatitis in a mammal. Thus, one of ordinary skill in the art could use the method to treat hepatitis C in a human with a reasonable expectation of success.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Desmyter et al. (Texas Reports on Biology and Medicine 35:516-522, 1977) taken with and Yano et al., (YANO 1) (US Patent No. 5,298,614, cited on prior 892) as applied to claim 5, and further in view of Liaw (J. Gastroenterol. Hepatol. 1997, 12:S346-53).

However, Desmyter and YANO 1 do not specifically teach using the method to treat hepatitis C.

However, at the invention was made, Liaw teaches that interferon (IFN) is the only approved and widely used agent for the treatment of HBV, HCV, and HDV (page S346).

At the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to combine the teaching of Desmyter and YANO 1 in further view of Liaw for using Poly IC in a method for treating hepatitis C in a human. One of ordinary skill in the art would have been motivated to combine the teachings and use the method to treat hepatitis C in a human because Liaw teaches that IFN is approved for treating HBV and HCV and Poly IC is

known to one of ordinary skill in the art for producing a substantial amount of IFN in vivo for treating hepatitis in a mammal. Thus, one of ordinary skill in the art could use the method to treat hepatitis C in a human with a reasonable expectation of success.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Conclusion

During the interview with Eugene Rzucidlo on 11/15/04, the examiner notified Mr. Rzucidlo that prior art rejection(s) of record would be overcome by adding limitations directed to concentrations and/or regimens set on page 8 of the instant specification to the claims. In addition, the examiner notified Mr. Rzucidlo that the added limitations would require further search and consideration because these limitations were not examined in a prior office action.

After a search of a prior art for the added limitations, the examiner has determined that the limitations added to the claims are not novel as reflected in the new prior art rejections.

Applicant's invention is directed to a method of treating hepatitis in a human using a complex comprising a cationic liposome, a phospholipid, and Poly IC, wherein the Poly IC has reduced toxicity by reducing the length of Poly IC to within the range of 100 to 500 bp. However, treating hepatitis in a human using an interferon or an interferon inducer, including dsRNA (Poly IC) was already known in the prior art as exemplified by Desmyter. In addition, reducing toxicity of Poly IC in vivo by using Poly IC that has a length within the range of 100 to 500 bp was already known in the prior art (YANO1). In addition, delivering Poly IC in a complex to a human, wherein the complex comprises 2-O-(2-diethylaminoethyl)carbamoyl-1,3,-

O-dioleoylglycerol and a phospholipid was already known in the prior art (YANO2). Furthermore, the prior art (e.g., Bever and Desmyter) already taught the limitations for using concentration with the range of 1 μ g to 50 mg of Poly IC and varying the time point of delivering Poly IC to a human. Thus, the claimed invention is not considered patentable over the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

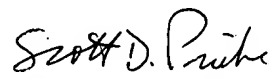
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER